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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,535	07/09/2001	James C. Keith JR.	GIN-6006B4	6877

7590 09/26/2002

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/26/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,535	KEITH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the claims 1-6, 8-18, and 31-36 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claimed methods require the detection of distinct target molecules. Further, the kit claims are improperly joined as the kits require distinct target molecules, i.e. reagents for detecting mRNA and reagents for detecting protein. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, and 4-6, drawn to methods for identifying a compound that modulates expression of syncytin, classified in Class 435, subclass 6.

II. Claims 1, 2, 5 and 6, drawn to methods for identifying compounds that modulate cellular localization of syncytin, classified in Class 435, subclass 4.

III. Claims 1, 3, 5 and 6, drawn to methods for identifying compounds that modulate syncytin activity by assaying for cell fusion, classified in Class 435, subclass 7.1.

IV. Claim 7, drawn to a compound which modulates syncytin expression, classified in Class 514, subclass 2.

V. Claims 8-18, drawn to methods of diagnosis by assaying for mRNA, classified in Class 435, subclass 6.

VI. Claims 8-18, drawn to methods of diagnosis by assaying for protein, classified in Class 435, subclass 7.1.

VII. Claims 19-30, drawn to methods of treatment using a compound that modulates syncytin, classified in Class 514, subclass 2.

VIII. Claims 31-33, 35, and 36, drawn to kits comprising reagents for detecting mRNA, classified in Class 536, subclass 23.5.

IX. Claims 31-32, 34-36, drawn to kits comprising reagents for detecting protein, wherein the reagent includes antibodies, classified in Class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, V, VI and VII are each drawn to patentably distinct methods. Each method requires the use of distinct reagents and involves performing different method steps and/or has a different objective. In particular, the method of invention I requires assaying for the expression level of syncytin, for example, by using protein binding assays or mRNA detection assays to achieve the objective of identifying a compound that modulates syncytin. Invention II requires assaying for a change in the cellular localization of syncytin and thereby requires performing method steps which assay for the cellular location of syncytin, to achieve the objective of identifying a compound that modulates syncytin. Invention III requires assaying for the fusion between 2 cells and thereby requires the use of 2 cells and reagents for detecting the

fusion of 2 cells, to achieve the objective of identifying a compound that modulates syncytin. Invention V requires the use of probes or primers and involves performing hybridization or amplification steps in order to achieve the objective of diagnosing preeclampsia. Invention VI requires the use of proteins and involves performing ligand binding assays or Western blotting in order to achieve the objective of diagnosing preeclampsia. Invention VII requires the use of a modulator and involves treating an individual with a modulator in order to achieve the objective of treating preeclampsia.

Inventions I and IV, II and IV, and III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the compounds of invention IV can be used in a materially different process, such as for therapeutic purposes.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention VIII can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

Inventions I and IX, II and IX and III and IX are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention IX can be used in a materially different process, such as for generating antibodies or for therapeutic methods.

Inventions II and VIII and III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention VIII are not required to practice the methods of inventions II or III.

Inventions IV and V and IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compounds of invention IV are not required to practice the methods of inventions V or VI.

Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the compounds of invention IV can be used in a materially

different process, such as for screening assays.

Inventions IV and VIII and IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compounds of invention IV are not disclosed as capable of use together with the kits of invention VIII or IX and the compounds of invention IV are functionally and structurally different from the components of the kits of inventions VIII and IX.

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the kits of invention IX are not required to practice the methods of inventions VI.

Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the kits of invention VIII are not required to practice the methods of inventions VI.

Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the kits of invention VIII can be used in a materially different

process, such as for screening for compounds that modulate syncytin expression.

Inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the kits of invention IX can be used in a materially different process, such as for screening for compounds that modulate syncytin expression.

Inventions VII and VIII and VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the kits of invention VIII and IX are not required to practice the methods of inventions VII.

Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the binding partners of invention VII can be used in a materially different process, such as for therapeutic purposes.

Inventions VIII and IX are patentably distinct in structure and physicochemical properties. Invention VIII is drawn to kits comprising nucleic acids whereas invention IX is

drawn to kits comprising antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the antibodies may be utilized in ligand binding assays. Synthesis of the antibodies of invention IX does not require the particular products of the nucleic acids of invention VIII.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because the inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

September 24, 2002

CARLA J. MYERS
PRIMARY EXAMINER